

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

**IN RE HUMAN TISSUE PRODUCTS
LIABILITY LITIGATION**

Civ. No. 06-135
MDL No. 1763

**THIS DOCUMENT RELATES TO:
ALL CASES**

OPINION

HON. WILLIAM J. MARTINI

WILLIAM J. MARTINI, U.S.D.J.:

This matter comes before the Court on Plaintiffs' motion for reconsideration of the Final Order of Dismissal, entered on December 10, 2008.¹ This Final Order applied the Court's October 22, 2008 Opinion and Order ("the Science First opinion") to the individual Plaintiffs (hereinafter the "Recipient Plaintiffs") in this multidistrict litigation. Plaintiffs now move for reconsideration of the Final Order, arguing generally: (1) that certain Recipient Plaintiffs were included on the Final Order in error; (2) that those Recipient Plaintiffs who failed to affirmatively plead bone failure and/or bacterial infection claims should be permitted to amend their complaints to include such claims;

¹ This Opinion also will address two motions presenting issues similar to those raised by Plaintiffs in their motion for reconsideration: (1) Plaintiff Christine Cleveland's motion for relief under Fed. R. Civ. P. 60(a) from the Final Order of Dismissal, *see* Civ. No. 06-135, Docket No. 739, and (2) Plaintiffs Don and Kathy Stanley's motion for leave to file a second amended complaint, *see* Civ. No. 06-3642, Docket No. 15.

and 3) that the Court should issue an amended order, stating that unprocessed frozen bone tissue may transmit disease. There was no oral argument. Fed. R. Civ. P. 78. For the reasons stated below, Plaintiffs' motion is **GRANTED IN PART** and **DENIED IN PART**.

I. BACKGROUND

Since the facts are well-known to the parties at this point, the Court will discuss them only briefly here. The complaints in this action were brought by both individual plaintiffs and representatives of putative class actions, alleging injury from the implantation of human tissue illegally obtained by the now-defunct Biomedical Tissue Services ("BTS"). Defendants include the principals in the criminal operation, the funeral homes that provided BTS access to the corpses from which the tissue was obtained, the companies that processed tissue recovered from cadavers by BTS into various medical products, the distributors of the processed tissue products, and the hospitals and medical personnel who transplanted the processed tissue product. Certain of these Defendants jointly moved for summary judgment on the issue of general causation for the various tort claims asserted by the Recipient Plaintiffs, who allegedly suffered harm from the processed tissue product.

On October 22, 2008, this Court granted Defendants summary judgment on their motion with regard to the transmission and incubation of certain diseases. Specifically, the Court held that Plaintiffs failed to provide any reliable evidence to support their

claims of general causation with respect to the transmission of HIV, hepatitis B virus (HBV), hepatitis C virus (HCV), cancer, and syphilis through unprocessed human bone tissue, stored at room temperature for thirty days or more before implantation into an individual. In addition, the Court held that Plaintiffs failed to put forth any reliable evidence to support their claims that those plaintiffs who tested negative for HIV, HBV, HCV, and syphilis six months after exposure to potentially infectious bone tissue were capable of developing these diseases subsequently from such tissue. Finally, the Court held that Plaintiffs failed to support their general causation claims pertaining to the transmission of prion disease through human cadaveric bone tissue. Accordingly, on October 22, 2008, the Court granted Defendants' summary judgment motion as to these specific issues.

The Court then held hearings on October 31, 2008 and December 1, 2008 to discuss the application of this Science First decision to the individual Recipient Plaintiff cases. At these hearings, the Court stated that those cases specifically alleging “brittle bone”² or infection claims would not be dismissed in the Final Order; however, the Court instructed Plaintiffs that they were to identify those cases affirmatively pleading such claims. In addition, the Court heard arguments by Plaintiffs that they should be permitted to amend their complaints to include additional “bone failure” or infection counts.

Based on the Science First opinion, as well as the information and representations

² “Brittle bone” is used interchangeably with “bone failure,” which Plaintiffs use to connote a problem with the structural integrity of the implanted tissue. *See, e.g.* Docket No. 204.

provided by the parties, the Court entered its Final Order on December 10, 2008, which dismissed complaints meeting the following criteria:

- Recipient Plaintiffs whose tissue was kept at room temperature for thirty or more days (listed in Exhibit A³ to the Final Order);
- Recipient Plaintiffs who tested negative for certain diseases (HBV, HCV, HIV, and syphilis) six months or more after implant surgery (listed in Exhibit B to the Final Order); or,
- Recipient Plaintiffs who have any claims involving the transmission of prion disease.

To the extent that a Recipient Plaintiff affirmatively pled a claim of "bone failure" or bacterial infection, those claims alone were not dismissed, but instead were administratively stayed.

II. DISCUSSION

Plaintiffs now move for reconsideration of the Final Order, arguing specifically that: 1) any LifeCell case in which the Recipient Plaintiff did not test negative for disease six months or more after the date of implant should be removed from both Exhibits A & B to the Final Order; 2) any Recipient Plaintiffs testing positive for disease should be removed from Exhibit B; 3) any Recipient Plaintiffs affirmatively pleading either "bone

³ At the Court's direction, Defendant RTI submitted a proposed Final Order with Exhibit A, which listed each Recipient Plaintiff who received tissue kept at room temperature for 30 days or more. In addition, this proposed Final Order included Exhibit B, listing each Recipient Plaintiff who had tested negative for HBV, HCV, HIV, and syphilis six months or more after implant surgery. Plaintiffs purportedly provided comments on the proposed Order; however, to the Court's knowledge, Plaintiffs did not object to the inclusion of particular Recipient Plaintiffs on Exhibits A & B prior to the issuance of the Order.

failure” or bacterial infection should have those claims alone administratively stayed; 4) Plaintiffs should be allowed to amend their complaints to assert additional “bone failure” and/or bacterial infection claims; and, 5) the Court should issue an amended order, stating that frozen unprocessed bone tissue may transmit disease. These arguments will be addressed in turn.

A. Motion for Reconsideration Standard

The "purpose of a motion for reconsideration is to correct manifest errors of law or fact or to present newly discovered evidence." *Harsco Corp. v. Zlotnicki*, 779 F.2d 906, 909 (3d Cir. 1985). Such a motion “may not be used to relitigate old matters, nor to raise arguments or present evidence that could have been raised prior to the entry of judgment.” *P. Schoenfeld Asset Mgmt. LLC v. Cendant Corp.*, 161 F. Supp. 2d 349, 352 (D.N.J. 2001). Accordingly, a motion under Rule 7.1(i) may be granted if: (1) “an intervening change in the controlling law has occurred; (2) evidence not previously available has become available; or (3) it is necessary to correct a clear error of law or prevent manifest injustice.” *Database Am., Inc. v. Bellsouth Adver. & Pub. Corp.*, 825 F. Supp. 1216, 1220 (D.N.J. 1993); *see also N. River Ins. Co. v. CIGNA Reins. Co.*, 52 F.3d 1194, 1218 (3d Cir. 1995). Because reconsideration of a judgment after its entry is an extraordinary remedy, requests pursuant to Rule 7.1(i) are to be granted “sparingly.” *P. Schoenfeld Asset Mgmt.*, 161 F. Supp. 2d at 352-53.

B. Removal of LifeCell Recipient Plaintiffs from Exhibit A

As an initial matter, Plaintiffs request that the Court “amend its order and not dismiss any LifeCell case where the Plaintiff did not have negative blood work six (6) months or more after the date of surgery.” Pls’ Moving Br. at 1. Specifically, Plaintiffs allege that five LifeCell Recipient Plaintiffs⁴ should not have been included in the Final Order. Plaintiffs argue that dismissal of these particular complaints was improper, since there is evidence casting doubt on whether the LifeCell stored the implants these Recipient Plaintiffs received at room temperature for thirty or more days.

In support of this allegation, Plaintiffs point to an affidavit submitted by Darrell Roberts, Vice President, Quality for LifeCell (“the Roberts Affidavit”). *See* Certification of Jason E. Macias, December 24, 2008 (“Macias Cert.”), Ex. I. In this November 24, 2008 affidavit, Roberts provides a list of those Recipient Plaintiffs who received LifeCell tissue. This list specifies the “days at room temperature” for each implant, which is defined as “thaw date to date of implant.”

Plaintiffs contend that representations on LifeCell’s website call into question whether LifeCell tissue is stored at “room temperature” or refrigerated. For example, the LifeCell website states that “Alloderm tissue grafts must be stored under refrigeration at 1°C - 10°C (34°F - 50°F) to preserve the product’s shelf life.” Macias Cert., Ex. II. Further, the website states that “Alloderm tissue grafts are shipped at ambient temperature

⁴ Recipient Plaintiffs Johnson (Civ. No. 07-6170), Horner (Civ. No. 07-5198), Elson (Civ. No. 07-4337), Oliver (Civ. No. 07-4703), and Pfaff (Civ. No. 07-4744).

via overnight delivery service within 24 hours of order placement. *Although AlloDerm will ship out of refrigeration, this limited exposure will not affect product efficacy or shelf life.*” Macias Cert., Ex. II (emphasis added). Based on LifeCell’s own representations on its website, it appears that LifeCell tissue may be stored at refrigerated temperatures. As such, the “thaw date,” in fact, may be the refrigeration date for these implants.

LifeCell's opposition did not rebut the accusation that its tissue was refrigerated; instead, LifeCell simply questioned the timing of Plaintiffs' objection.⁵ While LifeCell’s response is well-taken, it does little to help the Court determine whether these five particular Recipient Plaintiffs should be included on Exhibit A to the Final Order. The pertinent issue at this juncture is whether these LifeCell Recipient Plaintiffs received tissue stored at room temperature for at least thirty days. In light of the website representations presented by Plaintiffs on this motion, there appears to be a question of fact as to whether LifeCell tissue was stored at room temperature. As such, those five Recipient Plaintiff complaints identified by Plaintiffs cannot be placed at this time on Exhibit A,⁶ absent a demonstration that LifeCell’s storage methods comport with the

⁵ It bears noting that the Roberts Affidavit, listing the “days at room temperature” for each LifeCell implant, is dated November 28, 2008 – just one week before the Final Order was issued.

⁶ In addition, Plaintiffs Horner, Elson, Oliver, and Johnson should not be placed on Exhibit B. These three Recipient Plaintiffs each tested negative less than six months post-surgery and were not retested thereafter. Defendants respond that Plaintiffs' failure to get re-tested after six months should not salvage their complaints. While this argument is appealing, it nonetheless fails. The plain language of the Order dismisses those Plaintiffs who tested negative more than six months post-surgery. Horner, Elson and Oliver did not. Accordingly, Plaintiffs Horner, Elson,

language of the Final Order – i.e. that the tissue at issue here was stored at room temperature for thirty or more days. As such, the Court will reserve on Plaintiffs' request to remove these five Recipient Plaintiffs,⁷ pending the submission of supplemental briefing by Defendant LifeCell establishing that the tissue received by these five Recipient Plaintiffs was stored at room temperature thirty days prior to implant.

C. Removal of Recipient Plaintiffs Alleging Disease from Exhibit B

Plaintiffs allege that twenty-two Recipient Plaintiffs, listed on Exhibit B, tested positive for disease. *See* Macias Cert., Ex. XI (listing complaints). Defendants object to the timing of this allegation, arguing that Plaintiffs received a list of those Recipient Plaintiffs to be included on Exhibit B on November 7, 2008. Plaintiffs ostensibly reviewed this list and failed to object to the inclusion of these Recipient Plaintiffs until after the Final Order was entered over a month later. Further, Defendants argue that Plaintiffs' own complaints, fact sheets, and medical records belie the accuracy of their "disease" allegations. Again, while Defendants' arguments are appealing, for the most part, it appears that Plaintiffs are correct.

and Oliver should be removed from both Exhibit B. Plaintiff Pfaff tested negative more than six months after her implant surgery, *see* Pfaff Compl. ¶¶ 25, 29, and will remain on Exhibit B. Plaintiff Johnson will be discussed separately, *infra*.

⁷ This holding pertains only to those five LifeCell Recipient Plaintiffs identified by Plaintiffs in their motion. Since Plaintiffs had ample opportunity to identify an additional LifeCell Plaintiffs subject to the same tissue storage concerns, the Court will assume going forward that only these five currently identified were affected.

i. Hepatitis C

Plaintiffs argue that eight Recipient Plaintiffs⁸ included on Exhibit B tested positive for Hepatitis C. Defendants do not dispute that these Plaintiffs, with the exception of Recipient Plaintiff Gasser,⁹ were infected with HCV. Defendants argue that these Plaintiffs each either failed to substantiate their infection allegations or acquired these infections from another source before their surgeries. While this is an issue that merits further exploration, it is of no consequence on this motion. The Final Order clearly states that only those Plaintiffs testing negative for disease six months are dismissed. These Recipient Plaintiffs, tested positive for disease and thus shall be removed from Exhibit B.

ii. Hepatitis B and Hepatitis C Antibodies

Plaintiffs contend that twelve Recipient Plaintiffs¹⁰ should be removed from Exhibit B because they tested positive for HCV or HCB antibodies. Plaintiffs argue that testing positive for either an HBV or an HCV antibody is an indicator of infectivity and

⁸ Recipient Plaintiffs Gasser (Civ. No. 07-3838), Cosgrove (Civ. No. 07-4709), Kalmbach (Civ. No. 07-4766), Drew (Civ. No. 08-3554), Dillon (Civ. No. 07-4728), Green (Civ. No. 07-1422), Davenport (Civ. No. 06-5141), and Johnson (Civ. No. 07-6170).

⁹ Defendants RTI, Medtronic, and Tutogen argue that Gasser tested positive for HCV antibodies, not HCV infection. The Court does not have the information to evaluate this distinction at this time. *See infra* Point II.C.ii.

¹⁰ Recipient Plaintiffs Bowen (Civ. No. 06-5144), Straw (Civ. No. 06-3642), Severs (Civ. No. 07-1442), Chessier (Civ. No. 07-4107), Fuselier (Civ. No. 06-5146), Matheny (Civ. No. 07-4301), Dillard (Civ. No. 08-3799), Reedy (Civ. No. 08-2430), Scholes (Civ. No. 07-5634), Jennings (Civ. No. 08-2927), Harden (Civ. No. 07-1461), and Hufstetler (Civ. No. 07-1279).

should be viewed as testing positive for disease. Defendants disagree, countering that testing positive for an antibody is different than having an active infection. Whether the presence of antibodies signals infection appears to be a highly fact-specific inquiry for each particular Recipient Plaintiff. Since the Court has been given no briefing on this motion regarding antibody infectivity, it cannot make the determination whether testing positive for an antibody is more akin to testing positive or negative for disease. Due to this uncertainty, the Court cannot dismiss the complaints of these twelve Recipient Plaintiffs by listing them on Exhibit B at this time.

iii. Additional Recipient Plaintiffs

Plaintiffs contend that two additional Recipient Plaintiffs should be removed from Exhibit B – Recipient Plaintiffs Antoncic (Civ. No. 07-3247) and Robinson (Civ. No. 07-1458). For the reasons that follow, neither of these Recipient Plaintiffs will be removed.

Recipient Plaintiff Antoncic will remain on Exhibit B because she tested negative for disease six months or more after her implant surgery. While Antoncic tested positive on her initial screening for HIV II, a confirmatory test returned a negative result for HIV II and any other disease. *See* Declaration of Denise Brinker Bense (“Bense Decl.”), Ex. 21. Based on this information, the first test result appears to be a false positive. With the second confirmatory negative test, Antoncic fell under the Final Order’s six month dismissal criterion and was properly placed on Exhibit B.

While Plaintiffs argue that Recipient Plaintiff Robinson should be removed from Exhibit B, they provide no reason for his removal. Since the Court has no basis upon

which to reconsider the dismissal of Robinson’s complaint, it will remain on Exhibit B.

D. Pleadings Alleging “Bone Failure” or Bacterial Infection Claims

Plaintiffs contend that among the ailments allegedly afflicting recipients of BTS tissue are “bone failure” – or the structural failure of the implant – and bacterial infection. Under the terms of the Final Order, any “bone failure” or bacterial infection claims affirmatively pled by those Recipient Plaintiffs identified on Exhibits A and/or B were administratively stayed.¹¹

Plaintiffs make two arguments regarding these two classes of claims. First, they allege that the Court improperly dismissed fifteen complaints that affirmatively pled “bone failure” and/or bacterial infection. *See* Macias Cert., Ex. IX (listing complaints). As such, those complaints, if dismissed on other grounds, should be dismissed under FRCP 54(b) to allow the “bone failure” and infection claims to be stayed. Second, Plaintiffs argue that they should be allowed now to amend those complaints that do not affirmatively plead “bone failure” and infection to include such claims. These arguments will be addressed in turn.

i. Dismissal of Complaints Allegedly Pleading “Bone Failure” or Bacterial Infection

Plaintiffs argue that the Court improperly dismissed fifteen complaints¹² that

¹¹ Those complaints presenting more than one claim for relief and a claim for “bone failure” and/or bacterial infection were dismissed pursuant to Fed. R. Civ. P. 54(b) to allow the “bone failure” and bacterial infection claims to be stayed.

¹² Recipient Plaintiffs Bates (Civ. No. 06-5946), Fife (Civ. No. 06-3615), Castello (Civ. No. 06-5599), Bowie (Civ. No. 08-4311), Cleveland (Civ. No. 08-5773), Pfaff (Civ. No.

affirmatively pled “bone failure” and/or bacterial infection. As such, these complaints were dismissed pursuant to Fed. R. Civ. P. 56, while Plaintiffs contend that dismissal should have been pursuant to Fed. R. Civ. P. 54(b) to allow the “bone failure” and infection claims to be stayed. Defendants agree as to seven of these complaints.¹³

Review of these seven complaints reveals that they plead “bone failure” or infection claims; therefore, these claims alone are administratively stayed.

Defendants argue that the remaining seven¹⁴ complaints do not affirmatively plead “bone failure” or infection counts, and therefore should not be stayed. Defendants are correct as to three Recipient Plaintiffs – Cooper (Civ. No. 07-2176), Nelson (Civ. No. 07-2177), and Schroeder (Civ. No. 06-3649). Each of these Recipient Plaintiffs pled that their grafts were not healing properly. *See* Cooper Compl. ¶ 26, Nelson Compl. ¶ 26,

07-4744), Schroeder (Civ. No. 06-3649), Cooper (Civ. No. 07-2176), Nelson (Civ. No. 07-2177), Outten (Civ. No. 07-6056), Boerstler (Civ. No. 07-2172), Shepherd (Civ. No. 08-255), Rodgers (Civ. No. 08-2474), Houston (Civ. No. 07-4711), and Hagena (Civ. No. 07-304).

¹³ Bates (bone failure), Boerstler (bone failure), Bowie (bone failure), Fife (bone failure, infection), Houston (infection), and Shepherd (bone failure). While Defendants RTI and Medtronic appear to concede that the seventh Plaintiff – Cleveland – pled infection, Defendant Tutogen submitted extensive briefing in opposition to Cleveland's separate motion for relief under Fed. R. Civ. P. 60(a) from the Final Order, arguing, *inter alia*, that Cleveland never requested that her claims should be stayed prior to the entry of the Final Order. *See* Civ. No. 08-5773, Docket #8. The pertinent issue, however, is whether Cleveland pled infection. Since Cleveland did so, *see* Cleveland Am. Compl. ¶ 21, her infection claim is stayed.

¹⁴ Neither Plaintiffs nor Defendants make any argument as Plaintiff Hagena (Civ. No. 07-304) – the final Recipient Plaintiff of the fifteen marked by Plaintiffs as improperly excluded. After reviewing the Complaint, it appears that Hagena pled infection. *See* Hagena Compl. ¶ 9 (“The contaminated or infected bones caused Carla Hagena to suffer a severe infection in her neck.”). As such, Hagena's infection claim is stayed.

Schroeder Compl. ¶ 26 ("Plaintiff is emotionally distraught and outraged by having the stolen and improperly processed tissue or bone in his body, and Plaintiff's graft is not healing properly and in all reasonable medical probability will have to be replaced."). This nebulous assertion made by all three does not plead "bone failure" or some other problem with the structural integrity of their implants. As such, these three complaints were properly dismissed.¹⁵

The four remaining Recipient Plaintiffs – Castello (Civ. No. 06-5599), Pfaff (Civ. No. 07-4744), Outten (Civ. No. 07-6056), and Rodgers (Civ. No. 08-2474) – should not have been dismissed under Fed. R. Civ. P. 56. Recipient Plaintiffs Castello, Pfaff, and Outten each pled infection. *See* Castello Compl. ¶ 11 ("As a result of the negligent and other wrongful conduct of the Defendants, Richard Castello ... required treatment and surgery to treat him for infection and remove the graft ..."); Pfaff Compl. ¶ 30 ("As a direct and proximate result of the negligent and other wrongful conduct of Defendants, Plaintiff, Elizabeth Pfaff, suffered from and continues to suffer from a debilitating sepsis infection causing her to lose mobility in her legs and arms."); Outten Compl. ¶ 32 ("In May 2007, Plaintiff, Carol Outten was diagnosed with breast cancer. Plaintiff Carol Outten had to undergo lumpectomy surgery and has since suffered from numerous

¹⁵ Plaintiffs Don and Kathy Stanley allege that they pled a "bone failure" claim in their First Amended Complaint. *See* Civ. No. 06-3642, Docket No. 18. Like Plaintiffs Cooper, Nelson, and Schroeder, the Stanleys made only a nebulous assertion that falls short of affirmatively pleading "bone failure." The Stanleys plead only a "risk of disease, infection, and product failure." *See* Stanley First Am. Compl. ¶ 100. As such, their First Amended Complaint was properly dismissed.

infections."). As such, the complaints of Recipient Plaintiffs Castello, Pfaff, Outten, and Rodgers are dismissed under Fed. R. Civ. P. 54(b) to allow these infection claims to be administratively stayed.

Recipient Plaintiff Rodgers pled a disease not addressed by Final Order – “liver failure.” *See* Rodgers Am. Compl. ¶ 32. Accordingly, this claim by Recipient Plaintiff Rodgers will be stayed.

ii. Amendment of Pleadings to Include Additional “Bone Failure” or Infection Claims

Plaintiffs contend that they abstained from amending or supplementing their complaints to add newly-discovered “bone failure” and/or bacterial infection claims, in compliance with Judge Hedges’ January 31, 2007 order (“the Hedges Order”).¹⁶ Since they were complying with the Hedges Order, Plaintiffs argue that the Court's decision to prohibit further amendment of their complaints after the issuance of the Final Order was both arbitrary and not in accordance with Fed. R. Civ. P. 15. Defendants respond by pointing out that fifty-two Plaintiffs have filed amended complaints since November 2005. Of these fifty-two amended complaints, Defendants represent that twenty-seven were filed after the supposedly prohibitive Hedges Order.

Federal Rule of Civil Procedure 15(a) provides that leave to amend a pleading

¹⁶ The Hedges Order states: “All *pending* motions in the above-captioned MDL proceeding (both motions pending in donor cases and in recipient cases) other than the science first motions filed in the recipient cases be and they hereby are stayed until further order of the Court ... No *new* motions shall be filed (in either the donor or recipient cases) *pending leave of Court* ...”(emphasis added). Docket No. 225.

“shall be freely given when justice so requires.” Fed. R. Civ. P. 15(a). The decision to grant or deny leave to amend a pleading is within the discretion of the court. *Foman v. Davis*, 371 U.S. 178, 182 (1962). Rule 15(d) governs when a Plaintiff seeks to incorporate claims that occurred after the initial filing of the complaint. *See* Fed. R. Civ. P. 15(d) (“On motion and reasonable notice, the court may, on just terms, permit a party to serve a supplemental pleading setting out any transaction, occurrence, or event that happened after the date of the pleading to be supplemented.”). While Rule 15(d) lacks the same express mandate as Rule 15(a), courts in this District have construed subsection (d) to require a similarly liberal approach. *See Hassoun v. Cimmino*, 126 F. Supp. 2d. 353, 360 (D.N.J. 2000).

This liberal approach, however, pertains to pre-judgment motions to amend. Although Plaintiffs are correct that Rule 15 states that before judgment, a court should freely give leave to amend when justice so requires, after final judgment, leave to amend is viewed differently. As the Third Circuit has noted, “[t]he liberal standard announced in Fed. R. Civ. Proc. 15(a) becomes less flexible after a final judgment is entered.” *Werner v. Werner*, 267 F.3d 288, 296 (3d Cir. 2001). Post-judgment leave to amend will be granted only sparingly, and will be the “long-odds exception.” *Id.* (quoting *Dartmouth Review v. Dartmouth Coll.*, 889 F.2d 13, 22 (1st Cir.1989)); *see also Bressner v. Ambroziak*, 379 F.3d 478, 484 (7th Cir. 2004) (“At this juncture [after a judgment has been entered], the party making a ... motion so that it can amend its complaint had better provide the district court with a good reason to grant its motion.”) (quoting *Harris v. City*

of Auburn, 27 F.3d 1284, 1287 (7th Cir.1994)); *First Nat'l Bank v. Cont'l Illinois Nat'l Bank*, 933 F.2d 466, 468 (7th Cir.1991) ("[T]he presumption in favor of liberality in granting motions to amend ... is reversed after judgment has been entered."). When a party delays making a motion to amend until after summary judgment has been granted to the adverse party, courts have recognized that the interests in judicial economy and finality of litigation may become particularly compelling. *See, e.g., Diersen v. Chicago Car Exch.*, 110 F.3d 481, 489 (7th Cir.1997); *State Trading Corp. of India, Ltd. v. Assuranceforeningen Skuld*, 921 F.2d 409, 418 (2d Cir. 1990) ("When the moving party has had an opportunity to assert the amendment earlier, but has waited until after judgment before requesting leave, a court may exercise its discretion more exactly."); *Union Planters Nat'l Leasing Inc. v. Woods*, 687 F.2d 117, 121 (5th Cir.1982); *Dussouy v. Gulf Coast Inv. Corp.*, 660 F.2d 594, 598 n.2 (5th Cir.1981).

Plaintiffs' contention that the Hedges Order somehow barred them from amending their complaints is not sufficient to overcome these compelling interests and justify granting leave to amend at this late post-judgment stage. Notably, the Hedges Order did not bar the amendment of pleadings. In fact, the Hedges Order did not discuss amendment of pleadings. The Hedges Order stated that motions could be made with leave of the Court; therefore, consistent with the Hedges Order, Plaintiffs could have amended or supplemented their complaints with leave of the Court. These Recipient Plaintiffs simply did not do so.

In addition, Plaintiffs' request to amend or supplement their complaints is unduly

delayed. *See Foman v. Davis*, 371 U.S. 178, 182 (1962); *Cureton v. Nat'l Collegiate Athletic Ass'n*, 252 F.3d 267, 272-73 (3d Cir. 2001) (holding that where plaintiff's delay in seeking amendment is either undue, motivated by bad faith or prejudicial to the opposing party, a district court may exercise its discretion to deny leave to amend). In many cases, Plaintiffs are making this request years after their initial complaints were filed and only after their other claims were dismissed on summary judgment. While the mere passage of time does not require that a motion to amend a complaint be denied on grounds of delay, "at some point, the delay will become 'undue,' placing an unwarranted burden on the court, or will become 'prejudicial,' placing an unfair burden on the opposing party." *Adams v. Gould Inc.*, 739 F.2d 858, 868 (3d Cir. 1984). For example, delay may become undue when a movant has had previous opportunities to amend a complaint. *See Lorenz v. CSX Corp.*, 1 F.3d 1406, 1414 (3d Cir.1993) (finding a three-year lapse between filing of complaint and proposed amendment to be an "unreasonable" delay where plaintiff had "numerous opportunities" to amend). This is particularly true where the movant possessed the information with which to amend but did not do so. *USX Corp. v. Barnhart*, 395 F.3d 161, 168-69 (3d Cir. 2004) ("Appellants waited over three years to amend to contest these assignments and had notice of the assignments prior to filing both the original complaint and the first amended complaint. It was not an abuse of discretion for the District Court to deny leave to amend.")

Here, the facts with which Recipient Plaintiffs seek to amend were in their sole possession prior to, and during the pendency of, the cross-motions for summary

judgment; however, until their complaints were dismissed, Plaintiffs did not seek to add them. *See, e.g.,* Macias February 5, 2009 Cert., Ex. 3, Green Proposed First Am. Compl. ¶¶ 1, 3 (“[o]n or about June 20, 2003, Plaintiff underwent a lumbar laminectomy and fusion at L3-4 and L4-5 in which cadaver bone was used. Following this surgery he developed spinal fluid leakage and infection which required surgical repair on June 24, 2003; July 5, 2003; and again on July 24, 2003. ... In May 2004, Mr. Green’s x-rays indicated that his interbody graft was not solid and that one of the grafts at L5-1 had fractured.”).¹⁷ Plaintiffs were not prevented by Defendants or by the Court from unearthing the facts that they now seek to add to their complaints. *See Werner v. Werner*, 267 F.3d 288, 296 (3d Cir. 2001). In fact, Recipient Plaintiffs were the only individuals in this litigation aware of whether they developed “bone failure” or a bacterial infection, yet they sat on these facts until the final disposition of their complaints.

Summary judgment did not sneak up on these Recipient Plaintiffs. The motion was pending for well over a year. Certainly, during this extended period, it should have been in Plaintiffs' contemplation that they could lose on summary judgment, resulting in the

¹⁷ *See also* Macias February 5, 2009 Cert., Ex. 2, Amitsis Proposed First Am. Compl. ¶¶ 6, 8 (“Plaintiff ... underwent two oral surgical procedures to apply dental implants on August 29, 2005 and August 31, 2005 at the Union Dental Center in Clifton, New Jersey. ... Plaintiff, in fact, did sustain infections of the human bone transplants and bone graft procedure failed, and Plaintiff was forced to undergo additional subsequent medical procedures on December 27, 2005, February 27, 2006 and March 20, 2006.”); Macias February 5, 2009 Cert., Ex. 23, Lane Proposed First Am. Compl. ¶¶ 36, 44 (“On March 29, 2005, Plaintiff ... underwent surgery which included the implantation of an allograft product manufactured, sold and distributed by LifeCell. ... As a result of continuing problems experienced by Plaintiff with her implant and based on medical advice Plaintiff had the damaged, failed and improper allograft removed on May 17, 2006.”)

dismissal of their complaints. While it is understandable that Recipient Plaintiffs wish to amend or supplement their pleadings at this time to keep them viable, they had ample opportunity to do so before judgment. Having not done so, it is now simply too late, and their request is denied.¹⁸

E. Amended Order Regarding Frozen Tissue

Finally, Plaintiffs request that the Court issue an amended order, stating that frozen unprocessed bone tissue may transmit disease. While this Court indicated at the December 1, 2008 hearing that it would be willing to issue a short amended order to that effect, upon reconsideration, the utility – or lack thereof – of such an order militates against its issuance at this time.

Since there are no complaints pending that involve frozen, unprocessed and non-sterilized tissue,¹⁹ issuance of such an order at this point would be an advisory opinion on hypothetical cases. As the parties are well aware, “[t]he oldest and most consistent thread in the federal law of justiciability is that federal courts will not give advisory opinions.” *Coffin v. Malvern Fed. Sav. Bank*, 90 F.3d 851, 853 (3rd Cir. 1996). Beyond this advisory opinion concern, such an order arguably would be outside the scope of the Science First opinion. The Science First opinion spoke only to the infectivity of

¹⁸ Plaintiffs Don and Kathy Stanley moved separately for leave to file a second amended complaint on December 18, 2008. *See* Civ. No. 08-3642, Docket No. 15. For the reasons stated above, their motion is also denied.

¹⁹ Plaintiffs have not identified any such complaints, nor is the Court aware of any.

unprocessed tissue with regard to HCB, HCV, syphilis, cancer, and prions; however, Plaintiffs' requested order is open-ended and would appear to cover the entire gamut of disease. Since Plaintiffs' request both pertains to hypothetical cases and is broader than the scope of the Science First opinion, the Court now reconsiders and denies Plaintiffs' request for an amended order.

III. CONCLUSION

For the foregoing reasons, Plaintiffs' motion for reconsideration is **GRANTED IN PART** and **DENIED IN PART**. An appropriate Order follows this Opinion.

/s/ William J. Martini
WILLIAM J. MARTINI, U.S.D.J.